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| EXAMINER | |
|---|---|
| YAO, LEI | |

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| 1642 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/781,659 | ITOH ET AL. | |
| | Examiner | Art Unit | |
| | LEI YAO | 1642 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *2, 3, and 11-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 3, and 11-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/763,985.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

**Request for Continued Examination**

The request filed on 4/18/2008 for a Continued Examination (RCE) under 37 CFR 1.114 based on Application No. 10781659 is acceptable, and a RCE has been established. An action on the RCE follows.

Claims 1, and 4-10 are cancelled.

Claims 16-18 are added.

Claims 2, 3, and 11-18 are pending and under consideration for an isolated tumor antigen that is a partial peptide of SEQ ID NO: 2 and/or comprises the amino acid sequence of SEQ ID NO: 3 that bind to HLA-A24, and the composition and the agent comprising the peptide for treating a tumor.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the **second paragraph** of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c).

In the present instance, claim 18 is drawn to tumor antigen that is a partial peptide of the amino acids of SEQ ID NO: 2, wherein the peptide comprises a variant of SEQ ID NO: 3 having one or more amino acid substitution. SEQ ID NO: 3 is 10 amino acids located in the 109-118 of SEQ ID NO: 2. The claim recites the broad recitation of variant of SEQ ID NO: 3 having one or more amino acid substitution, and the claim also recites a partial peptide of a protein consisting of the amino acid sequence of SEQ ID NO: 2 which is the narrower statement of the range/limitation. By given the language, one skilled in the art would be not clear how a continued sequence of a partial peptide of SEQ ID NO: 2 encompass a variant of 108-119 of SEQ ID NO: 2 (SEQ ID NO: 3). Clarification is required.

The following is a quotation of the **first paragraph** of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Scope of enablement for any partial peptide of SEQ ID NO: 2 and variant of SEQ ID NO: 3

Claims 17 and 18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the tumor antigen being recognized by HAL-A24 restricted cytotoxic T cell that is a partial peptide of SEQ ID NO: 2 comprising the 10 amino acids of SEQ ID NO: 3, does not reasonably provide enablement for an tumor antigen that is any partial peptide of SEQ ID NO: 2 and a peptide comprising a variant of SEQ ID NO: 3 with one or more amino acid substitutions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is noted that SEQ ID NO: 2 is full length protein having 963 amino acids and SEQ ID NO: 3 is 10 amino acids at position 109-118 of the SEQ ID NO: 2.

The factor considered when determining if the disclosure satisfies the enablement requirement and whether any is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of necessary experimentation claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re wands*, 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir.1988).

The claims are broadly drawn to an isolated tumor antigen that is a partial peptide having at least 14 amino acid of SEQ ID NO: 2 or a variant of SEQ ID NO: 3 having one or more amino acid substitutions recognized by HLA-A24 and simulating the cytotoxic T-lymphocyte reaction again the HLA-A24 tumor cells. Thus, it would be expected that one of skill in the art would be able to make and use the antigen peptide for treating tumor by inducing the cytotoxic T-lymphocytes without undue experimentation.

The specification teaches tumor antigen protein (SEQ ID NO: 2) and the synthetic peptides that are the fragments of the tumor antigen protein (SEQ ID NO: 3-52) having about 10 amino acids with different amino acid sequence and their derivatives (SEQ ID NO: 53-64). The specification teaches that the peptides109-118 (SEQ ID NO: 3) and 315-323 (SEQ ID NO: 6) of the protein (SEQ ID NO: 2) bind to HLA-A24 restricted T cell and induce antigen specific cytotoxicity (CTL) to the HLA-A24 positive tumor

cells (examples 6 and 7). The specification further teaches that it is known that the peptides that are bound to and presented on HLA-A24 consist of 8 to 11 amino acids, although it may be a length of 14 or more amino acids (para 94).

One cannot extrapolate the teaching of the specification to the scope of the claims because 1) not all fragments of the protein listed in the specification have such function and 2) specification does not provide the structure/sequence that is essential for the function. Thus, one skilled in the art would not know how to use the claimed any partial peptides of SEQ ID NO: 2 having at least 14 amino acids or a variant of SEQ ID NO: 3 having substitutions being recognized by HLA-A24 restricted T cells and simulating cytotoxic T-lymphocyte reaction for the treating a tumor.

One skilled in the art has recognized that the protein of SEQ ID NO: 2 is a tumor antigen and the protein has ability to activate the HLA-A24-restrictied cytotoxic T Lymphocytes in cancer patient as evidenced by sequence search result (Yang et al., Cancer Research. Vol 59, page 4056-4063, 1999, IDS 2/20/2004 and sequence search result). However, when tested for the fragments of the protein, Yang et al., teach that only a few fragments of the protein were recognized by HLA-A24-restricted T cells and able to induce tumor specific CTL. On page 4060, figure 6, Yang et al disclose around 20 fragments of the SEQ ID NO: 2 from different locations and teach only the peptide VYDYNCHVDL (SEQ ID NO: 3), 109-118 of SEQ ID NO: 2, and peptide AYIDFEMKI (SEQ ID NO: 6), 315-323 of SEQ ID NO: 2, have the ability to induce the cytotoxicity of HLA-A24-restricted CTL (figure 6B). The peptides located in the different regions of protein such as 141-150, 188-197, 349-358, etc. have no such activity, and therefore, one skilled in the art would conclude that the specification does not provide enabled disclosure for claimed invention and undue quantity of experimentations would be required before one could practice claimed invention.

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to the partial peptide of SEQ ID NO: 2 or a variant of a functional peptide of SEQ ID NO: 3, one skilled in the art would be forced into under a quantity of experimentations in order to practice the broadly claimed invention.

2. Scope of enablement for binding to an HLA antigen and recognized by cytotoxic T Lymphocytes.

Claims 2 and 11-17 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the tumor antigen that is a partial peptide comprising the 10 amino acids of SEQ ID NO: 3 that binds to HLA-A24 antigen and is recognized by HLA-A24 restricted cytotoxic T-cell, does not reasonably provide enablement for the peptide that binds to other HLA antigen or is recognized by any other cytotoxic T-cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

It is noted that SEQ ID NO: 2 is full length protein having 963 amino acids and SEQ ID NO: 3 is 10 amino acids at position 109-118 of the SEQ ID NO: 2.

The factor considered when determining if the disclosure satisfies the enablement requirement and whether any is undue include, but are not limited to: 1) nature of the invention, 2) state of the prior art, 3) relative skill of those in the art, 4) level of predictability in the art, 5) existence of working examples, 6) breadth of necessary experimentation claims, 7) amount of direction or guidance by the inventor, and 8) quantity of experimentation needed to make or use the invention. *In re wands,* 858 F.2d 731, 737.8 USPQ2d 1400, 1404 (Fed. Cir.1988).

The claims are broadly drawn to an isolated tumor antigen that is a partial peptide comprising the amino acids of SEQ ID NO: 3 or variant thereof or having at least 14 amino acid at any location of SEQ ID NO: 2 recognized by a cytotoxic T cell and simulating cytotoxic T-lymphocyte reaction for any tumor. Thus, it would be expected that one of skill in the art would be able to make and use the antigen peptide for treating any tumor by inducing a cytotoxic T-lymphocyte (CTL) activity beyond than the HLA-A24 restricted T cells.

The specification teaches tumor antigen protein (SEQ ID NO: 2) and the synthetic peptides that are the fragments of SEQ ID NO: 2 having about 10 amino acids with different amino acid sequences and their derivatives. The specification teaches that the peptides 109-118 (SEQ ID NO: 3) and 315-323 (SEQ ID NO: 6) of the protein of SEQ ID NO: 2 could induce HLA-A24 antigen specific CTL cytotoxicity to the HLA-A24 positive tumor cells (examples 6 and 7).

One cannot extrapolate the teaching of the specification to the scope of the claims because the

specification does not teach that any partial peptide of SEQ ID NO: 2 or the partial peptides comprising the SEQ ID NO: 3 bind to any other HLA antigen or recognized by any other T-cell other the HLA-A24 restricted to induce the cytotoxicity for any HLA-A24 negative tumor cell. Thus, one skilled in the art would not know how to use the claimed peptide to simulate any cytotoxic T-lymphocyte reaction for the treating a tumor.

One skilled in the art has also recognized that the protein of SEQ ID NO: 2 is a tumor antigen and has ability to induce the HLA-A24-restrictied cytotoxic T Lymphocytes in cancer patient as evidenced by sequence search result (Yang et al., Cancer Research. Vol 59, page 4056-4063, 1999, IDS 2/20/2004 and sequence search result). However, Yang et al., teach that the fragments of the tumor antigen recognize only HLA-24 or HLA-A2/24 antigen and have minimal induction for other HLA restricted CTL activity such as HLA-A11 or HLA-A26 etc. (see table 2). Therefore, one skilled in the art would conclude that the neither specification nor art provides an enabled disclosure for claimed any partial peptide of SEQ ID NO: 2 or the partial peptide comprising the SEQ ID NO: 3 and its variant for the function recited in the claims and undue a quantity of experimentations would be required before one could practice claimed invention.

In view of the lack of guidance, lack of examples, and lack of predictability associated with regard to the partial peptide of SEQ ID NO: 2 or a variant of a functional peptide of SEQ ID NO: 3 for the activity of inducing CTL cell and treating any tumors, one skilled in the art would be forced into under experimentation in order to practice the broadly claimed invention.

3. Written Description rejection-variant of SEQ ID NO: 3.

Claim 18 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claim is broadly drawn to a partial peptide of SEQ ID NO: 2 that comprise a variant of amino acids of SEQ ID NO: 3 having one or more amino acid substitutions and binds to an HLA-A24 to activate

cytotoxic T lymphocytes. Thus, the claims are inclusive of a genus of variant peptide of SEQ ID NO: 3 with amino acid substitution at any location of the peptide, which encompass significant structural and functional dissimilarity and diversity as compared to the peptide of SEQ ID NO: 3 for the claimed function.

The specification teaches a 10 amino acid peptide of SEQ ID NO: 3 that is a partial peptide of SEQ ID NO: 2 and can have one or more residue substitutions that is recognized by cytotoxic T cell and retaining the HLA-A24 binding motif. The specification provides only the species of SEQ ID NO: 3 having such function and induces cytotoxicity of T cells for lysing a tumor cell. The specification neither reduces to practice any variant of SEQ ID NO: 3 as claimed, nor provides functional characteristic indicating which or where the amino acid changed in the sequence and the activity could be retained. As such the specification as filed does not provides adequate written description support for the claimed variants of SEQ ID NO: 3 and one of skill in the art would reasonably conclude that the inventor(s), at the time the application was filed, **did not have** possession of the claimed invention.

A description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or by describing structural features common the genus that "constitute a substantial portion of the genus." See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997): "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNA, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristic, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613".

The court has since clarified that this standard applies to compounds other than cDNAs. See University of Rochester v. G.D. Searle & Co., Inc., F.3d ,2004 WL 260813, at *9 (Fed.Cir.Feb. 13, 2004). The specification provides neither a representative number of the peptide that encompass the genus that reveal the roles of inducing cytotoxicity of HLA-A24 restricted T cell nor does it provide a description of structural features that are common to the polypeptide are associated with such activity.

*Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan **cannot envision the detailed** chemical structure(s) and functional attribute(s) of the encompassed genus of the peptides, and therefore conception is not achieved until **reduction to practice has occurred**, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only the partial peptide of SEQ ID NO: 2 comprising the peptide of SEQ ID NO: 3, but not the full breadth of the claims, meets the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

It is noted that applicant's arguments for the rejections under USC 112 1st are moot in view of the amendment and new ground rejections above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18 is rejected under 35 U.S.C. 102(b) as being anticipated by Kausch et al (Plan Physiol vol 107, page 669-670, 1995) or as evidenced by sequence search result for SEQ ID NO: 3.

The claim is drawn to an isolated tumor antigen peptide that is a partial peptide of a protein consisting of the amino acid sequence of SEQ ID NO: 2, wherein the peptide comprises the amino acid sequence of SEQ ID NO: 3 or a variant of SEQ ID NO: 3 having one or more amino acid substitutions retaining a HLA-A24 binding motif and binds to an HLA antigen and is recognized by cytotoxic T lymphocytes.

Due to the indefiniteness of the term "partial peptide of SEQ ID NO: 102 having one or more amino acid substitution" as stated above, the Office, for the art purpose, interprets that claimed peptide is a variant of SEQ ID NO: 3, or a variant of partial peptide of SEQ ID NO: 2.

Kausch et al., disclose a Lipozygenase protein that comprises a variant of SEQ ID NO: 3 with three amino acid substitution as evidenced by search result (attached). The peptide disclosed in the reference reads on the claimed peptide variant of SEQ ID NO: 3, which would inherently have the function of HLA-A24 binding and is recognized by cytotoxic T Lymphocyte.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Copending application 10505955:

The rejection of claims 2, 3, and 11-18 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 35 and 43 of copending Application No. 10505955 is withdrawn since the product claims 35 and 43 in the amendments after 10/27/2007 are withdrawn from examination as being non-elected invention and applicant elected the method of using the product. Thus, the claims are subjected to the new rejection as the following:

Claims 2-3 and 11-18 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 47-51, 53 and 56 of copending Application No. 10505955 ('955). Although the conflicting claims are not identical, they are not patentably distinct from each other and rejection.

The instant claims 2-3 and 16-18 are drawn to a tumor antigen peptide that is partial peptide of SEQ ID NO: 2 or the peptide comprising an amino acid sequence of SEQ ID NO: 3 or its variants. Claims 11-15 are drawn to a pharmaceutical composition and diagnostic agent having active component of SEQ ID NO: 3 or a partial peptide of SEQ ID NO: 2 comprising the SEQ ID NO: 3.

Claim 47-51, 53 and 56 of copending application 10505955 ('955) are drawn to a method of treating a disease comprising administering a patient with an antigen peptide, wherein the patient is HLA-A24 positive. The antigen peptide of SEQ ID NO: 21 in the application '955 is identical to instant claimed peptide (SEQ ID NO: 3) comprised by SEQ ID NO: 2 as evidenced by the sequence search result provided in the Office action dated 1/9/2007. Thus the difference between the two sets of claims is the peptide with intent use and the method of using the peptide. However, the method of using the same peptide anticipates or obvious over the claimed peptides. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to claim the tumor antigen peptide that is partial peptide of SEQ ID NO: 2 or a peptide of SEQ ID NO: 2 comprising the amino acids of SEQ ID NO: 3 based on the method of using the peptide. One of ordinary skill in the art at the time the invention was made would have been motivated with reasonable expectation of success to arrive the

instant invention because the peptide of SEQ ID NO: 2 or peptide comprising SEQ ID NO: 3 has been used for treating a tumor comprising the tumor expressing HLA-A24 antigen.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-6.00pm Monday-Thursday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Lei Yao, Ph.D./
Examiner, Art Unit 1642

/Larry R. Helms/
Supervisory Patent Examiner, Art Unit 1643